

BEST AVAILABLE COPY

AMENDMENTS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Original) Process for the preparation of a retarded release formulation for oral use in tablet form, containing at least one active principle with a pharmaceutical, dietary or alimentary action and at least one hydrogenated fatty acid, as the vehicle, in amounts of between 5 and 30%, relative to the weight of the formulation, wherein:

- (a) said at least one active principle is mixed with said at least one hydrogenated fatty acid in the melted state in the weight proportions defined above;
- (b) the blend thus obtained is cooled to 5-20 °C and then granulated using a granulator having holes with a diameter of between 1 and 4 mm;
- (c) the granules thus obtained are then compressed.

2. (Original) The process according to claim 1, wherein said hydrogenated fatty acid is present in amounts between 10 and 20%, relative to the weight of the formulation.

3. (Original) The process according to claim 1, wherein the blend in point (b) is cooled to 10°C -12°C.

4. (Original) The process according to claim 1, wherein the blend in point (b) is granulated using a granulator having holes with a diameter of between 1 and 2 mm.

5. (Presently Amended) The process according to claim 1 wherein:

[(d)] before the mixing in point (a), said at least one active principle is premixed at ambient temperature with [said] excipients and/or adjuvants [in the weight proportions defined above;]

[(e)] the mixture thus obtained is mixed with said at least one fat and/or phospholipid in the melted state in the weight proportions defined above;

[(f)] the blend thus obtained is cooled to 5-20°C, preferably to 10°C -12°C, and then granulated using a granulator having holes with a diameter of between 1 and 4 mm, preferably between 1 and 2 mm;

[(g)] the granules thus obtained are then compressed].

6. (Presently Amended) A formulation obtainable by the process according to any of claims 1-5, or 14-15.

7. (Presently Amended) A formulation according to claim 6, characterized in that said at least one hydrogenated fatty acid has a chain comprising between 3 and 20 carbon atoms, [preferably between 14 and 8 carbon atoms,] or mixtures thereof.

8. (Original) A formulation according to claim 6, characterized in that said at least one hydrogenated fatty acid is hydrogenated palm oil.

9. (Presently Amended) A formulation according to claim 6, characterized in that said at least one active principle is present in an amount of 70-95%, [preferably 75-90%,] relative to the weight of the formulation, and in that said at least one active principle and said at least one hydrogenated fatty acid make up 100% by weight of the formulation.

10. (Presently Amended) A formulation according to claim 6, characterized by containing: (a) from 10 to 50% by weight, of at least one active principle with a pharmaceutical, dietary or alimentary action; (5) from 5 to 30% by weight of said fatty acid [at least one fat] and (c) excipients [excipients] and/or adjuvants, the sum of the components (a), (b) and (c) making up 100% by weight of the formulation.

11. (Original) A formulation according to claim 10, characterized by containing from 30 to 50% by weight of component (a).

12. (Original) A formulation according to claim 10, characterized by containing from 20 to 30% by weight of component (b).

13. (Original) A formulation according to claim 6, characterized in that said at least one active principle with a therapeutic action is selected from non-steroid and steroid anti-inflammatory drugs, tranquilizers, sleeping pills, anti-hypertensive, anti-histaminic and anti-asthmatic drugs and in that said at least one active principle with a dietary or alimentary action is selected from the group consisting of lactic acid microorganisms, beer yeasts, either as such or containing living cells, vitamins, minerals, amino acids, vegetable extracts, and derivatives thereof.

14. (New) The process according to claim 1, wherein the blend in point (b) thus obtained is cooled to 10°C -12°C.

15. (New) The process according to claim 1, wherein the blend in point (b) thus obtained is granulated after cooling using a granulator having holes with a diameter of between 1 and 2 mm.

16. (New) A formulation according to claim 6, characterized in that said at least one hydrogenated fatty acid has a chain comprising between 8 and 14 carbon atoms, or mixtures thereof.

17. (New) A formulation according to claim 6, characterized in that said at least one active principle is present in an amount of 75-90%, relative to the weight of the formulation, and in that said at least one active principle and said at least one hydrogenated fatty acid make up 100% by weight of the formulation.
